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FORM**

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Total Number of Pages in This Submission

24

Application Number

10/760,091

Filing Date

January 16, 2004

First Named Inventor

Thomas L. CANTOR

Art Unit

1641

Examiner Name

C. Cheu

Attorney Docket Number

532212000624

**ENCLOSURES (Check all that apply)**☐ Fee Transmittal Form☐ Fee Attached☐ Amendment/Reply☐ After Final☐ Affidavits/declaration(s)☐ Extension of Time Request☐ Express Abandonment Request☒ Information Disclosure Statement –  
Supplemental (11 pages)☐ Certified Copy of Priority  
Document(s)☐ Reply to Missing Parts/  
Incomplete Application☐ Reply to Missing Parts under  
37 CFR 1.52 or 1.53☐ Drawing(s)☐ Licensing-related Papers☐ Petition☐ Petition to Convert to a  
Provisional Application☐ Power of Attorney, Revocation  
Change of Correspondence Address☐ Terminal Disclaimer☐ Request for Refund☐ CD, Number of CD(s) \_\_\_\_\_☐ Landscape Table on CD☐ After Allowance Communication  
to TC☐ Appeal Communication to Board of  
Appeals and Interferences☐ Appeal Communication to TC  
(Appeal Notice, Brief, Reply Brief)☐ Proprietary Information☐ Status Letter☒ Other Enclosure(s) (please  
Identify below):Form PTO/SB/08A/B  
(6 pages + duplicate)

References (125)

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**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name

MORRISON &amp; FOERSTER LLP

Signature

Printed name

Peng Chen

Date

July 3, 2008

Reg. No.

43,543

I hereby certify that this paper is being deposited with the U.S. Postal Service as Express Mail, Airbill Nos. Box #1 – EV 956953002 US, Box #2 – EV 956953016 US, Box #3 – EV 956953020 US, on the date shown below in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: July 3, 2008

Signature:

(Anthony Matson)

I hereby certify that this paper is being deposited with the U.S. Postal Service as Express Mail, Airbill Nos. Box #1 - EV 956953002 US, Box #2 - EV 956953016 US, Box #3 - EV 956953020 US, on the date shown below in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: July 3, 2008

Signature: A. Matson

(Anthony Matson)



Patent

Docket No. 532212000624

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Re Patent Application of:  
Thomas L. CANTOR et al.

Serial No.: 10/760,091

Filing Date: January 16, 2004

For: METHODS FOR DIFFERENTIATING  
AND MONITORING PARATHYROID  
AND BONE STATUS RELATED  
DISEASES

Examiner: C. Cheu

Group Art Unit: 1641

**SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of the foreign document and non-patent literature documents are also submitted herewith. The Examiner is requested to consider and make these documents of record.

Document numbers 11-40 and 124-131 listed on the attached Form PTO/SB/08a/b are from Patent Interference No. 105,575 (MPT), between Application No. 10/641,780 and U.S. Patent No. 6,838,264. Application No. 10/641,780 is related to the present application.

Document numbers 94-96 are from the prosecution history of Application No. 11/437,428. Applicants filed the present application to provoke interference with Application No. 09/898,398. Application No. 11/437,428 claims the benefit of 09/898,398.

Document numbers 97-100 are from the prosecution history of Application No. 10/168,185. Applicants filed related Application No. 10/945,608 to provoke interference with Application No. 10/168,185. Document number 107 is from the prosecution of related Application No. 10/945,608.

Document numbers 101-104 are from the prosecution history of Application No. 10/954,695. Applicants filed related Application No. 10/641,780 to provoke interference with Application No. 09/730,174. Application No. 10/954,695 claims the benefit of Application No. 09/730,174. Document number 105 is from the prosecution history of Application No. 10/998,927, which also claims the benefit of 09/730,174.

Document numbers 41-60, 85-90, 108, and 123 are from *Scantibodies Laboratory, Inc. v. Immutopics, Inc.*, currently pending in the United States District Court for the Central District of California, Case No. CV 04-08871 MRP (MANx). This litigation involves U.S. Patent No. 6,689,566 (the '566 patent). The present application is Continuation of U.S. Patent No. 6,743,590, which is a Continuation-in-Part of U.S. Patent No. 6,689,566. Scantibodies Laboratory, Inc. is the assignee of the present application. Document numbers 61-70 are from the prosecution history of U.S. Patent No. 6,689,566. Document numbers 71, 72, 78-81, 106, and 133 are from the Reexamination of U.S. Patent No. 6,689,566, which has Control No.'s 90/007,685 and 90/007,732.

The defendant in that litigation, Immutopics, Inc., has asserted non-infringement, invalidity and unenforceability of the '566 patent and has submitted various documents related to its non-infringement, invalidity and unenforceability assertions in that litigation. In the Supplemental Information Disclosure Statement submitted on December 14, 2007, applicants submitted the following Immutopics' documents from that litigation:

- Memorandum of Points and Authorities in Support of Defendants' and Counterclaimants' Motion for Summary Judgment for Failing to Disclose the Best Mode, filed November 13, 2007;
- Declaration of Matthew A. Newboles in Support of Defendants' and Counterclaimants' Motion for Summary Judgment for Failing to Disclose the Best Mode, filed November 13, 2007;
- Memorandum of Points and Authorities in Support of Defendants' and Counterclaimants' Motion for Summary Judgment of Patent Invalidity for Violation of On Sale Bar and for Obviousness over the Prior Art, filed November 13, 2007;
- Declaration of Matthew A. Newboles in Support of Defendants' and Counterclaimants' Motion for Summary Judgment of Patent Invalidity for Violation of On Sale Bar and for Obviousness over the Prior Art, filed November 13, 2007;
- Memorandum of Points and Authorities in Support of Defendants' and Counterclaimants' Motion for Summary Judgment of Patent Invalidity for Lack of Enablement, filed November 13, 2007;
- Declaration of Matthew A. Newboles in Support of Defendants' and Counterclaimants' Motion for Summary Judgment of Patent Invalidity for Lack of Enablement, filed November 13, 2007;
- Memorandum of Points and Authorities in Support of Defendants' and Counterclaimants' Motion for Summary Judgment of Non-Infringement of the '566 Patent, filed November 13, 2007; and

- Declaration of Jeffrey Lavigne in Support of Defendants' and Counterclaimants' Motion for Summary Judgment Based on Non-Infringement of the '566 Patent, filed November 13, 2007.

With respect to the "Best Mode" issue, Immutopics alleged that the inventors of the '566 patent used a PTH (1-9) peptide to affinity purify an anti-PTH antibody before the Application No. 09/231,422, which issued as the '566 patent, was filed and the '566 patent fails to disclose the use of a PTH (1-9) peptide to affinity purify an anti-PTH antibody.

In the present application, the applicants submitted, on March 23, 2007, as part of a Response to a Non-Final Office Action, a replacement Figure 5, in which the portion of the title referring to Antibody As Tracer is amended to "with PTH 1-[[8]]<sub>9</sub> Antibody as Tracer." A Declaration of Thomas L. Cantor pursuant to 37 C.F.R § 1.132 (Cantor Decl.), explaining the reason for amending Figure 5, was also submitted with the March 23, 2007 Response.

In the reexamination of the '566 patent (Control No. 90/007,685 and 90/007,732), the patent owner also submitted a replacement Figure 5 as part of a Response to the Non-Final Office Action on July 24, 2006. The Examiner in the reexamination of the '566 patent objected to the amendment of Figure 5 in the September 21, 2006 Final Office Action as adding new matter. (*See* the September 21, 2006 Final Office Action at pages 6-9.) The patent owner withdrew the amendment of Figure 5 as part of the November 10, 2006 Response to the Final Office Action in the reexamination of the '566 patent. (*See* the November 10, 2006 Response to the Final Office Action at page 13.) Patent owner's July 24, 2006 Response to the Non-Final Office Action was submitted as document number 719 in the Supplemental Information Disclosure Statement on September 29, 2006. The Examiner considered this document in the Office Action dated October 23, 2006. The September 21, 2006 Final Office Action was submitted as document number 721 in the Supplemental Information Disclosure Statement on September 29, 2006. The Examiner also considered this document in the Office Action dated October 23, 2006. Patent owner's November 10, 2006 Response to the Final Office Action in the reexamination of the '566 patent was submitted as document number 55 in the Supplemental Information Disclosure Statement on April 4, 2007. The Examiner considered this document in the Office Action dated June 15, 2007.

In the Supplemental Information Disclosure Statement submitted on September 29, 2006, applicants submitted document numbers 209-228, 231-251, and 516-580 from the *Scantibodies Laboratory, Inc. v. Immutopics, Inc.*, litigation. Applicants pointed out to the Examiner on page 5:

- Document numbers 209-228, 231-251, and 516-580 are from a pending civil action for patent infringement based on the '566 patent: *Scantibodies v. Immutopics*. Applicants wish to bring the Examiner's attention to the following papers from this proceeding:
  - Defendants' Answer to Plaintiff's Complaint and Counterclaims, filed December 3, 2004 (Document No. 213 in the present Form PTO/SB/08a/b), in which unenforceability of the '566 patent is alleged;
  - Defendants' First Amended Answer to Plaintiff's Complaint and Counterclaims, filed December 21, 2004 (Document No. 215 in the present Form PTO/SB/08a/b), in which unenforceability of the '566 patent is alleged;
  - Defendants' Second Amended Answer to Plaintiff's Complaint and Counterclaims, filed December 31, 2004 (Document No. 216 in the present Form PTO/SB/08a/b), in which unenforceability of the '566 patent is alleged; and
  - Plaintiff's Reply to Defendants' Counterclaims, filed January 27, 2005 (Document No. 217 in the present Form PTO/SB/08a/b), in which the alleged unenforceability of the '566 patent is denied.

The Examiner considered all of the documents submitted with the September 29, 2006 Supplemental Information Disclosure Statement in the Office Action dated October 23, 2006.

Document number 108 is a Claim Construction Order from *Scantibodies Laboratory, Inc. v. Immutopics, Inc.* The Court reached the following construction of terms:

1. “Specific for” is defined as **exhibiting significantly greater binding affinity for the PTH(2-8) region of whole PTH than for the PTH(9-84) region.**

2. “Specifically binds to whole parathyroid hormone but does not specifically bind to an interfering non-(1-84) parathyroid hormone fragment” cannot be defined by the Court because the level of specificity for whole PTH over interfering fragments is indeterminate. An absolute standard, which would preclude all binding to interfering fragments, is inappropriate. The proper standard is clearly relative, but the Court is unable to determine a measure of the degree or relativity.

3. “Not detecting an interfering non-(1-84) parathyroid hormone fragment” is similarly indeterminate.

Document number 123 is an Order granting and denying Immutopics’ various summary judgment motions from *Scantibodies Laboratory, Inc. v. Immutopics, Inc.* The court granted Immutopics’ Motion for Summary Judgment of Non-Infringement of U.S. Patent No. 6,689,566 (the motion was submitted under seal in the Supplemental Information Disclosure Statement dated December 14, 2007 as document number 83). The court denied Immutopics’ Motion for Summary Judgment for Failing to Disclose the Best Mode (the motion was submitted under seal in the Supplemental Information Disclosure Statement dated December 14, 2007 as document number 77). The court denied Immutopics’ Motion for Summary Judgment of Patent Invalidity for Lack of Enablement (the motion was submitted under seal in the Supplemental Information Disclosure Statement dated December 14, 2007 as document number 81). The court denied Immutopics’ Motion for Summary Judgment of Patent Invalidity for Violation of On Sale Bar and for Obviousness (the motion was submitted under seal in the Supplemental Information Disclosure Statement dated December 14, 2007 as document number 79).

Document numbers 73, 74, and 82 are from an opposition against EP Patent No. 1,151,307, which is related to the present application. The opposition was based on the following references:

- TAMPE et al., Journal of Immunoassay (1992) 13:1-13
- MAGERLEIN et al., Arzneim.-Forsch./Drug Res. (1998) 48(I):199-204
- MAGERLEIN et al., Arzneim.-Forsch./Drug Res. (1998) 48(II):738-787
- LOGUE et al., Journal of Immunological Methods (1991) 137:159-166
- WOOD, Annu. Clin. Biochem. (1992) 29:11-21
- WINGANDER et al., GBF Monographs (1988) 167-176
- CAPORALE and ROSENBLATT, Advances in Experimental Medicine and Biology (1986) 208:315-327
- FISHER et al., Journal of Clinical Investigation (1974) 54:1382-1394
- MAGERLEIN et al., European Journal of Pharmacological Sciences (1994) 154
- WO 96/10041 (US 6,030,790)
- LEPAGE et al., Clinical Chemistry (1998) 44:805-809
- MARX et al., J. Biol. Chem. (1995) 15194-15202

Document numbers 75-77, 93, and 132 are from the prosecution of related Application No. 10/617,489.

Document number 83 is an English translation of the decision denying the final appeal regarding the invalidation of JP Patent No. 3457004. As previously disclosed, Applicants commenced an invalidation proceeding in Japan against JP Patent No. 3457004. Applicants previously indicated that the JPO invalidated JP Patent No. 3457004 (for example, see page 13 of



the IDS dated September 29, 2006). Actually, all of the claims of N-terminal antibodies and its production method (Claim 1 and Claims 3-6) became invalid. However, the claims of PTH 1-37 assay method (Claim 2 and Claims 7-10) are still alive, because PTH 1-37 assay methods claims were not adjudicated at the Japanese Supreme Court.

Document number 109 is a Non-Final Office Action from related Application No. 11/799,726. Document numbers 1-7 and 110 were cited by the Examiner in the Office Action. Document number 8 is the published application for Application No. 11/799,726.

Document number 9 is the published application for related Application No. 11/894,367. Document numbers 111-122 are from the prosecution history of other applications filed by the Applicants.

Document number 134 is a European Search Report from Application No. EP 06 00 8181, which is related to the present application. Document number 10 was cited in the EP Search Report and has not been previously disclosed (the remaining documents cited in the search report have all been previously disclosed).

U.S. Patent Application Serial No. 10/641,780 (the '780 application), filed August 15, 2003, is a continuation of U.S. Patent Application Serial No. 09/344,639 (the '639 application), filed June 26, 1999, now U.S. Patent No. 6,743,590, which is a continuation-in-part of U.S. Patent Application Serial No. 09/231,422 (the '422 application), filed January 14, 1999, now U.S. Patent No. 6,689,566. The '780 application is currently involved in an interference, Patent Interference No. 105,575 (MPT), with Immutopics' U.S. Patent No. 6,838,264 B2 ('264 patent).

Immutopics submitted Zahradnik List of Motions on October 11, 2007, in which Zahradnik alleges that the allowed claims of application number 10/641,780 are invalid and unenforceable. Applicants submitted Zahradnik List of Motions (as Document No. 19) in Supplemental Information Disclosure Statement on October 19, 2007. Immutoipcs also submitted the following motions in the interference on December 14, 2007:

- Zahradnik Substantive Motion 1 (Motion for Judgment Under 35 U.S. C. § 135(b)), filed December 14, 2007 (submitted herewith as document number 22)
- Zahradnik Substantive Motion 2 (Judgment for No Interference in Fact), filed December 14, 2007 (submitted herewith as document number 23)
- Zahradnik Substantive Motion 3 (Judgment for Lack of Written Description), filed December 14, 2007 (submitted herewith as document number 24)
- Zahradnik Substantive Motion 4 (Judgment for Lack of Enablement), filed December 14, 2007 (submitted herewith as document number 25)

Applicants filed the following responses on March 21, 2008:

- Cantor Opposition 1 (Opposition to Motion for Judgment Under 35 U.S.C. § 135(b)), Patent Interference No. 105,575 (MPT), filed March 21, 2008 (submitted herewith as document number 30)
- Cantor Opposition 2 (Opposition to Motion for Judgment of No Interference-in-Fact), Patent Interference No. 105,575 (MPT), filed March 21, 2008 (submitted herewith as document number 31)
- Cantor Opposition to Zahradnik Motion 3, Judgment for Lack of Written Description, Patent Interference No. 105,575 (MPT), filed March 21, 2008 (submitted herewith as document number 32)
- Cantor Opposition to Zahradnik Motion 4, Judgment for Lack of Enablement, Patent Interference No. 105,575 (MPT), filed March 21, 2008 (submitted herewith as document number 33)

Immutopics filed the following replies on May 19, 2008:

- Zahradnik Reply 1 (Reply to Cantor Opposition to Zahradnik Motion 1 - § 135(b)) from Patent Interference No. 105,575 (MPT), filed May 19, 2008 (submitted herewith as document number 128)
- Zahradnik Reply 2 (Reply to Cantor Opposition to Zahradnik Motion 2 – No Interference-In-Fact) from Patent Interference No. 105,575 (MPT), filed May 19, 2008 (submitted herewith as document number 129)
- Zahradnik Reply 3 (Reply to Cantor Opposition to Zahradnik Motion 3 – Written Description) from Patent Interference No. 105,575 (MPT), filed May 19, 2008 (submitted herewith as document number 130)
- Zahradnik Reply 4 (Reply to Cantor Opposition to Zahradnik Motion 4 – Enablement) from Patent Interference No. 105,575 (MPT), filed May 19, 2008 (submitted herewith as document number 131)

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☒ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☐ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
- ☐ A fee is required. A check in the amount of \_\_\_ is enclosed.
- ☐ A fee is required. Accordingly, a Fee is included.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.

☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.

☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of \_\_ is enclosed.

☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 532212000624.

Dated: July 3, 2008

Respectfully submitted,

By: 

Peng Chen

Registration No.: 43,543

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